APR - 3 2018

UNITED STATES DISTRICT COURT EASTERN DISTRICT OF MISSOURI EASTERN DIVISION

| UNITED STATES OF AMERICA, |) | | |
|----------------------------------|---|-----|--|
| Plaintiff, |) | ; | 4:18CR00279 AGF/NAB |
| v. |) | No. | The state of the s |
| BRIJ R. VAID and DONNA A. WALDO, |) | | |
| , |) | | |
| Defendants. |) | | |

INDICTMENT

The Grand Jury charges that:

The Defendants

- 1. At all times relevant to this Indictment, defendant Brij R. Vaid ("Dr. Vaid"), was a resident of St. Louis County, Missouri, within the Eastern Division of the Eastern District of Missouri. Dr. Vaid was a medical doctor, and he operated several medical offices in St. Louis County, Missouri.
- 2. At all times relevant to this Indictment, defendant Donna A. Waldo, a/k/a Donna Ann Schimmelpfennig-Waldo ("Waldo"), was a resident of St. Louis County, Missouri, within the Eastern Division of the Eastern District of Missouri. Waldo was a family nurse practitioner and advanced practice registered nurse ("APRN"). Waldo worked under the supervision of Dr. Vaid at his medical offices in St. Louis County, Missouri.

Health Care Benefit Programs

3. The United States Department of Health and Human Services, through the Centers for Medicare and Medicaid Services ("CMS"), administered the Medicare and Medicaid Programs. Medicare and Medicaid were federal health care benefit programs within the meaning of 18 U.S.C. § 24(b), and these programs provide medical benefits, items, and services to elderly, disabled, and low income citizens. Medicare and Medicaid reimbursed health care providers for

covered health services that they provide to beneficiaries. As a "basic condition" of Medicare payment, any services billed by the provider must have first been furnished by a provider that was qualified to have payment made for the services. 42 C.F.R. § 424.5(a)(2). In order to receive reimbursement from Medicare, as enrolled providers, defendants were required by federal regulation to certify to the accuracy, completeness and truthfulness of all data related to any payments. 42 C.F.R. 423.505(k). Moreover, Medicare did not pay for items and services that were not reasonable and necessary for the diagnosis or treatment of illness or injury, or to improve the functioning of a malformed body member. 42 U.S.C. § 1395y.

- 4. To receive program reimbursement, providers must submit an appropriate application and execute a written provider agreement. The provider agreement obligates the provider to know, understand, and follow all program regulations and rules. After successful completion of the application process, Medicare and Medicaid assign the provider a unique provider number, which is a necessary identifier for billing purposes.
- 5. Defendant Dr. Vaid and defendant Waldo both signed Medicare Enrollment Applications. Defendants' Medicare provider enrollment applications contained a "Certification Statement" generally obligating the defendants to abide by Medicare laws and regulations and avoid submitting false claims to Medicare. Defendants' Medicare provider applications included the following agreements by the defendants:

I agree to abide by the Medicare laws, regulations, and program instructions that apply to this supplier. The Medicare laws, regulations, and program instructions are available through the Medicare contractor.

I will not knowingly present or cause to be presented a false or fraudulent claim for payment by Medicare, and I will not submit claims with deliberate ignorance or reckless disregard of their truth or falsity.

Dr. Vaid made similar commitments to Medicaid when enrolling in that program, while Waldo was not enrolled in Medicaid during 2014-15.

Billing the Programs with CPT Procedure Codes

- 6. When presenting claims to Medicare, Medicaid, and other insurers, providers use the Physicians Current Procedural Terminology codes, often called "CPT" codes, to describe the service they provided. CPT codes are developed by the American Medical Association and physicians of every specialty, who determine appropriate definitions for the CPT codes. By submitting claims using these CPT codes, providers represent to Medicare, Medicaid, and other insurers that the services described by the codes were, in fact, provided.
- 7. Reimbursement rates for the CPT codes are set through a "fee schedule" created by Medicare. The fee schedule outlines the maximum amount the government will reimburse the provider for a given service. The fee for a given service may vary depending on the type of health care professional providing the service.
- 8. Medicare uses CPT codes 99211-215 for the billing of office visits by physicians, with these codes covering services for the various lengths of time that a physician typically spends face-to-face with the patient. 99211 involves payment for a visit with a physician typically lasting five minutes with minimal presenting problems by the patient. The CPT discussion for 99211 notes some office visits billed under this code "may not require the presence of a physician." The other office visit codes, 99212-215, involve timeframes between 10-40 minutes, with the CPT discussion for each of these codes specifically stating that "the physician" typically spends the relevant time periods specified in each of these codes "face-to-face with the patient and/or family."
- 9. Medicare and Medicaid pay health care providers a set fee for each office visit provided under CPT codes 99211-15. Physicians receive higher reimbursement for providing

office visits than physician assistants, nurse practitioners, or APRNs under Medicare's rules and regulations.

Dr. Vaid's Awareness of Medicare Billing Problems

- 10. On or about June 6, 2012, Dr. Vaid received a comparative billing report from the Medicare program that provided him with billing data regarding his practice, as well as a list of program references that explained how to properly bill under CPT codes 99211-15. Among other issues, the report advised Dr. Vaid that his practice was billing CPT Code 99214 at a rate over seven times what his peers were billing.
- 11. On or about May 9, 2014, Dr. Vaid received an Operational Assessment Report from a consultant. A "key finding" of the report was that Dr. Vaid had potential compliance concerns relating to over-coding office visits. A "key recommendation" of the report was that Dr. Vaid should implement a documentation and coding audit regarding his office visit billing. The report further noted that at least according to the billing trends, Dr. Vaid and Waldo had productivity levels 3.5 and 2 times higher than 90% of their peers. The consultant's report specifically highlighted unusual CPT code 99214 billing patterns at the practice as "notably higher" than what Dr. Vaid's peers were billing.

Prescription Drugs that Contain "Controlled Substances"

- 12. Dr. Vaid had a Drug Enforcement Administration ("DEA") Registration Number, which authorized him to prescribe controlled substances in Schedules II through V since May 1992. Waldo does not have a DEA registration number, and has not previously applied for a number.
- 13. The Controlled Substances Act ("CSA"), Title 21, United States Code, Section 801, et seq., and its implementing regulations set forth which drugs and other substances are defined by law as "controlled substances." Those controlled substances are then assigned to one

of five schedules – Schedule I, II, III, IV, or V – depending on their potential for abuse, likelihood of physical or psychological dependency, accepted medical use, and accepted safety for use under medical supervision. A substance listed on Schedule I has a higher abuse potential than a substance on Schedule II. The abuse potential decreases as the Schedule numbers decrease.

- 14. Schedule I drugs or substances have no currently accepted medical use and have a high potential for abuse. They are the most dangerous drugs of all the drug schedules with potentially severe psychological or physical dependence. Schedule I drugs cannot legally be prescribed. Examples are heroin and ecstasy.
- 15. Schedule II drugs or substances have some accepted medical use, but with severe restrictions, and have a high potential for abuse, with use potentially leading to severe psychological or physical dependence. These drugs are also considered dangerous, and abuse can lead to addiction, overdose, and sometimes death. Examples are Percocet®, Opana®, and Adderall®.
- 16. Schedule III drugs or substances have a moderate to low potential for physical and psychological dependence, less than Schedule II drugs and more than Schedule IV. An example is ketamine.
- 17. Schedule IV drugs or substances have a low potential for abuse and low risk of dependence. Examples are Xanax® and Valium®.
- 18. Title 21, Code of Federal Regulations, Section 1306.04(a) states that a valid prescription for a controlled substance must be issued for a legitimate medical purpose by an individual practitioner acting in the usual course of his professional practice. A prescription not issued in the usual course of professional practice, or in legitimate and authorized research, is not a prescription within the meaning and intent of Section 309 of the CSA (21 U.S.C. § 829), and

the person knowingly issuing it shall be subject to the penalties provided for violations of the provisions of law relating to controlled substances.

Dr. Vaid's Prior Problems with Controlled Substances

19. On August 11, 2014, Dr. Vaid signed a settlement agreement with the Missouri State Board of Registration for the Healing Arts. In the settlement agreement, Dr. Vaid agreed that he had violated several controlled substances laws involving hydrocodone and other drugs, including failing to keep records regarding who received controlled substances from him. Dr. Vaid further agreed to comply in the future with all federal and state drugs laws, rules, and regulations.

Controlled Substances and Nurse Practitioners

20. Nurse practitioners generally cannot prescribe drugs containing Schedule II controlled substances, such as Percocet®, Morphine (e.g. Opana®), and Adderall®. After they successfully apply for and receive a DEA registration, nurse practitioners may prescribe drugs containing Schedule IV controlled substances (e.g. Xanax® and Valium®) under narrow circumstances. To do so, the nurse practitioners must use their own DEA registration number while also ensuring that the prescription contains less than a five day supply of drugs and is not automatically re-fillable. 21 U.S.C. § 829(a)-(b); RSMO §§ 334.104(2), 334.747.

Medicare Coverage for Services by Nurse Practitioners

21. Medicare covers services furnished by nurse practitioners when they act within the scope of practice authorized to practice by the State where the services are rendered and when the nurse practitioner works in collaboration with a physician. 42 C.F.R. § 410.75.

"Collaboration" is a process in which a nurse practitioner works with one or more physicians to deliver health care services within the scope of the nurse practitioner's expertise with medical

direction and appropriate supervision as provided for in jointly developed guidelines or other mechanisms as provided by the law of the State in which the services are performed.

- 22. In Missouri, a collaborating physician is responsible at all times for the oversight of the activities of a nurse practitioner with which he is collaborating. A collaborating physician accepts responsibility for any primary care services rendered by the nurse practitioner. V.A.M.S. § 334.036(5); § 335.016(2). A collaborating physician enters into a written agreement with a nurse practitioner to delegate his authority to provide treatment or dispense drugs, and any delegation must be consistent with the nurse practitioner's scope of practice. V.A.M.S. § 334.037(1). No physician assistant can practice or attempt to practice without physician supervision, or in any location where the supervising physician is not immediately available for consultation, assistance, and intervention. V.A.M.S. § 334.735(5).
- document titled "collaborative practice agreement with advanced practice registered nurse." In that document, Dr. Vaid delegated his authority to deliver certain health care services and treatments. Waldo agreed that she would not under any circumstances prescribe controlled substances. Waldo further agreed that she would administer or dispense controlled substances under the direction and supervision of Dr. Vaid only after a case by case determination of the patient's needs following verbal consultation between them, with the consultation recorded in the patient's chart and co-signed by Dr. Vaid. Waldo agreed to practice at Dr. Vaid's Tesson Ferry office location, and maintain a geographic proximity of zero miles with Dr. Vaid when delivering health care services under his supervision. Dr. Vaid agreed to be immediately available at all times for consultation, and to review the health care and prescribing practices of Waldo at least once every two weeks.

COUNT ONE

The Conspiracy

- 24. The Grand Jury adopts paragraphs 1-23 as and for paragraph 24.
- 25. From on or about April 3, 2013 through on or about February 28, 2015, in St. Louis County, Missouri, in the Eastern Division of the Eastern District of Missouri, and elsewhere, defendants,

BRIJ R. VAID and DONNA WALDO,

and others known and unknown to the Grand Jury, did knowingly and willfully agree and conspire with others to commit the following offense against the United States, specifically making or presenting false claims, in violation of 18 U.S.C. § 287.

Purpose of the Conspiracy

26. Defendants Dr. Vaid and Waldo, and others known and unknown to the Grand

Jury, conspired to make false and fraudulent representations to Medicare and Medicaid regarding

office visits and prescription drugs containing controlled substance for patients in order to make

money and generate profit.

Manner and Means of the Conspiracy

- 27. The manner and means employed by defendants and others to effect the object of the conspiracy were as follows:
- a. Dr. Vaid had a large number of patients who received Schedule II controlled substance prescriptions typically every 30 days. These Schedule II drugs included Oxycodone®, Hydrocodone, Opana®, and Adderall®. Dr. Vaid often issued additional prescriptions for other drugs in Schedule IV, often anti-anxiety drugs like Xanax®. At all times relevant to this

Indictment, Dr. Vaid was the only person at his office who had the credentials to legally prescribe drugs with controlled substances in Schedule II.

- b. Dr. Vaid traveled frequently, and was out of the State of Missouri or outside of the United States repeatedly during timeframes when his medical offices were open and seeing patients. During 2011-15, Dr. Vaid traveled to Texas, Florida, California, Maryland, Washington, D.C., Pennsylvania, Colorado, New Jersey, and Louisiana. Dr. Vaid also visited India and Canada during 2011-15.
- c. Even when he was in town, Dr. Vaid had multiple medical office locations at different locations as well as hospital duties, meaning he often was not in geographic proximity to the nurse practitioners that he employed to see his patients. Even when he was in the same office with other staff, he typically had his own full schedule of patients to see.
- d. Accordingly, given the number of patients needing drugs and his own scheduling challenges, Dr. Vaid often signed numerous prescriptions for controlled substances in advance of patients' visits, before patients had even visited the office and had an examination and medical evaluation. Dr. Vaid would use his appointment schedule to determine which patients were coming in to his office, and then have staff write out multiple prescriptions using whatever the patients had received during their last visits. Dr. Vaid instructed his staff, including Waldo, to provide these pre-signed prescriptions for controlled substances to patients later, in his absence.
- e. In an attempt to document these visits, Dr. Vaid, Waldo, and others created medical records. Given the volume of patients coming through Dr. Vaid's offices, it was difficult for Dr. Vaid and his staff to spend significant amounts of time with each patient on the daily schedule. Given the number of patients and the appointment schedule, Dr. Vaid and his staff used electronic medical systems to copy and "cut and paste" information from the previous month's visit into a new electronically generated visit note while leaving other sections of the

new medical record blank. For some visits, Dr. Vaid's medical files for his patients contained no documentation, or were missing prescriptions and drug test results.

- f. After these office visits, Dr. Vaid submitted or caused to be submitted claims to Medicare and Medicaid in which he represented to Medicare and Medicaid that he had met face to face with the patients and engaged in complex medical decision-making during the visits before his pre-signed prescriptions for controlled substances were issued in his absence.
- Dr. Vaid, Waldo and others at his medical practice repeatedly discussed an informal controlled substances policy that contained typical pain management practices. Under Dr. Vaid's policy, if a patient misplaced the drugs that Dr. Vaid prescribed, or claimed that the drugs were stolen, or claimed to "run out" of drugs "early" by consuming the prescribed drugs at higher dosages than what Dr. Vaid had prescribed (e.g. taking 30 days worth of medication in 15 days, taking 6 pills a day instead of 3), then those prescriptions would not be replaced. Further, under this policy, patients agreed to comply with urine drug testing. Dr. Vaid often ordered urine drug screens for his patients that were receiving controlled substances. Under the policy, if a patients' test results did not reflect the correct medication twice, then the patient was supposed to be discharged from Dr. Vaid's practice. Many patients claimed to have lost their medication, or consumed drugs quicker than the prescribed dosage. Defendants also received numerous drug test results that showed that the patients were repeatedly testing positive for illegal street drugs, and/or testing negative for the controlled substance drugs that Dr. Vaid was prescribing. After receiving these drug test results, Dr. Vaid and Waldo provided these patients with "replacement" prescriptions for controlled substances, and did not discharge them from the practice.

Overt Acts

- 28. In furtherance of the conspiracy, and to effectuate the purpose of the conspiracy, the defendants and others committed and caused to be committed the following overt acts, among others:
- a. On or about February 29, 2012, Waldo and Dr. Vaid signed a document titled "collaborative practice agreement with advanced practice registered nurse."
- b. On or about February 13, 2015, Dr. Vaid signed a prescription for Oxycontin, a Schedule II controlled substance, to patient M.H. in St. Louis County, Missouri, without first examining the patient, before he left for India.
- c. On or about February 20, 2015, Waldo provided a prescription for Oxycontin, a Schedule II controlled substance, to patient M.H. in St. Louis County, Missouri, while Dr. Vaid was in India.
- d. On or about June 11, 2014, Dr. Vaid signed a prescription for Aderall, a Schedule II controlled substance, for patient B.G. in St. Louis County, Missouri, without first examining the patient, before he left for New Jersey.
- e. On or about June 12, 2014, Waldo provided a prescription for Adderall, a
 Schedule II controlled substance, to patient B.G. in St. Louis County, Missouri, while Dr. Vaid
 was in New Jersey.
- f. On or about November 24, 2014, Dr. Vaid received a drug test result showing that B.R. was not taking Adderall®. On or about November 24, 2014, Dr. Vaid issued another prescription to B.R. for Adderall®.
- g. On or about December 24, 2014, Dr. Vaid received a drug test result showing that B.R. was taking Fentanyl, an opioid pain relief drug that is not listed in her medical record as one

of the drugs that Dr. Vaid was prescribing at that time. On or about December 24, 2014, Dr. Vaid issued B.R. two prescription for Oxymorphine®.

- h. On or about January 12, 2015, Dr. Vaid received a drug test result for B.R. showing positive results for cocaine and heroin. On or about January 21, 2015, Dr. Vaid issued another prescription to B.R. for Opana® and Adderral®.
- i. On or about January 15, 2015, Dr. Vaid received a drug test result for M.H. showing positive results for heroin but negative results for anti-anxiety "benzodiazepine" drugs like Clonazepam®. On or about January 15, 2015, Dr. Vaid issued another prescription to M.H. for Clonazepam® and Oxycodone®.
- j. On or about February 15, 2015, Dr. Vaid received a drug test result for M.H. showing positive results for hydromorphone, a drug not listed in his medical records as something he was prescribing for M.H. at that time. On or about February 20, 2015, Waldo provided M.H. with a prescription signed by Dr. Vaid for Oxycodone® and Oxycodone®.
- k. On or about February 14, 2015, Dr. Vaid signed a prescription for Opana® (extended release), a Schedule II controlled substance, for patient B.R. in St. Louis County, Missouri, to be provided to B.R. later while Dr. Vaid was in India.

All in violation of 18 U.S.C. §§ 371 and 2.

COUNTS TWO THROUGH SEVEN

Making and Presenting False Claims to the United States - (18 U.S.C. § 287)

29. The United States adopts paragraphs 1-23 and as for paragraph 29.

30. On or about the dates listed below, in St. Louis County, Missouri, in the Eastern Division of the Eastern District of Missouri, and elsewhere, defendant,

BRIJ R. VAID,

aided and abetted by others, and aiding and abetting others, made and presented to the Medicare and Medicaid programs claims upon and against the United States, that is, claims for face to face office visits under CPT code 99214 allegedly provided by Dr. Vaid, knowing that the claims were materially false, fictitious, and fraudulent in that defendant then and there well knew said statements and representations were false, fictitious, and fraudulent, as Dr. Vaid was outside of Missouri on those dates:

| Ct. | Patient | Program | Date | Location of Dr. Vaid on that Date | | | |
|-----|----------------------------|----------|-----------|-----------------------------------|--|--|--|
| 2 | G.J. | Medicaid | 2-27-2014 | India | | | |
| 3 | S.R. | Medicare | 2-28-2014 | India | | | |
| 4 | D.H. | Medicare | 3-4-2014 | India | | | |
| 5 | M.H. | Medicare | 3-4-2014 | India | | | |
| 6 | B.G. | Medicare | 6-12-2014 | New Jersey | | | |
| 7 | B.R. | Medicare | 6-12-2014 | New Jersey | | | |
| | A11: '14' C10 II G G C 207 | | | | | | |

All in violation of 18 U.S.C. § 287.

A TRUE BILL.

FOREPERSON

JEANNETTE S. GRAVISS Attorney for the United States, Acting Under Authority Conferred By 28 U.S.C. § 515

A.U.S.A. Andrew J. Lay, #39937 A.U.S.A. Gwendolyn Carroll